

FIELD OF THE INVENTION

BACKGROUND OF THE INVENTION

In addition, catheters that utilize a single type of ultrasonic transducer array only provide two dimensional information of the region examined by the catheter. Attempts

One approach is described in the article by Gussenhoven et al., entitled "Displacement Sensing Device Enabling Accurate Documentation of Catheter Tip Position," *Intravascular Ultrasound*, pg. 157-166 (1993), involves incrementally inserting a catheter having a radial scanning array into a region of interest to acquire multiple spaced two dimensional radial scans while monitoring the incremental increase in depth of penetration by passing the catheter between rollers which are attached to rotary encoders. The inclusion of mechanical sensing devices, however, compromises reliability of the measurements. In addition, the rollers may slip against the surface of the catheter thereby introducing error in the measurements.

Thus it is also desirable to provide a catheter that incorporates ultrasonic transducer technology that allows three dimensional images to be constructed of the region examined by the catheter in a precise but facile manner.

According to a first aspect of the present invention there is provided an ultrasonic catheter having a body having a longitudinal axis, a circumference and a distal end region, a first ultrasonic transducer array disposed in the distal end region of the body, and a second ultrasonic transducer array disposed in the distal end region of the body.

According to a second aspect of the present invention there is provided an ultrasonic system having an ultrasonic catheter including a body having a longitudinal axis, a circumference and a distal end region. The ultrasonic catheter includes a first ultrasonic transducer array disposed in the distal end region of the body and a second ultrasonic transducer array disposed in the distal end region of the body. A transmit beamformer and a receive beamformer are coupled to each of the first and second ultrasonic transducer arrays.

According to a third aspect of the present invention there is provided a method for registering image information acquired from an interior region of a patient. The method includes the steps of:

- (a) inserting a catheter having a body having a longitudinal axis, a circumference and a distal end region, a first ultrasonic transducer array disposed in the distal region of the body and a second phased ultrasonic transducer array disposed around the circumference of the distal end region of the body into a patient to image an interior region of the patient;
- (b) acquiring first two-dimensional image information in an image plane with the first ultrasonic transducer array;
- (c) acquiring tracking two-dimensional data information in a tracking plane oriented at a non-zero angle with respect to the image plane with the second ultrasonic transducer array;
- (d) repeating steps (b) and (c) after moving the catheter along a direction having a component of motion in the tracking plane;

(f) automatically using the component of motion determined in step (e) to register the first image information acquired in step (d) with the first image information acquired in step (b).

- (a) inserting a catheter having a body having a longitudinal axis, a circumference and a distal end region with a linear phased ultrasonic transducer array and a radial phased ultrasonic transducer array disposed thereon;
- (b) acquiring image information from the linear phased ultrasonic transducer array; and
- (c) acquiring image information from the radial phased ultrasonic transducer array.

- (a) inserting a catheter having a body having a longitudinal axis, a circumference and a distal end region, a linear phased ultrasonic transducer array disposed in the distal region of the body and a first radial phased ultrasonic transducer array disposed around the circumference of the distal end region of the body into a patient to image an interior region of the patient;
- (b) acquiring first two-dimensional image information in an image plane with the radial phased ultrasonic transducer array;
- (c) acquiring tracking two-dimensional data information in a tracking plane oriented at a non-zero angle with respect to the image plane with the linear phased ultrasonic transducer array;
- (d) repeating steps (b) and (c) after moving the catheter along a direction having a component of motion in the tracking plane;
- (e) automatically determining the component of motion based on a comparison of the tracking two-dimensional data information acquired in steps (c) and (d); and
- (f) automatically using the component of motion determined in step (e) to register the first image information acquired in step (d) with the first image information acquired in step (b).

FIG. 1 is a schematic view of a catheter according to a preferred embodiment of the present invention.

FIG. 3 illustrates a distal end region of a catheter according to a preferred embodiment of the present invention.

FIG. 5 is a further magnified view of the distal end region shown in FIG. 2.

FIG. 7 is a block diagram of an ultrasonic system according to a preferred embodiment of the present invention.

FIG. 9 illustrates the subset of beam data unwrapped.

FIG. 16 illustrates the distal region of still another preferred embodiment of a catheter according to the present invention.

The body 12 is preferably constructed of Pebax, manufactured by ELF ATOCHEM North America Inc. of

FIG. 2 is a magnified view of the distal end region 18 of the body 12 of the catheter 10 shown in FIG. 1. A first ultrasonic transducer array 20 ("first array 20") and a second ultrasonic transducer array 22 ("second array 22") are provided in the distal end region 18 of the catheter 10. In preferred embodiment the first array 20 is a linear phased array and the second array 22 is a radial phased array. In a preferred embodiment, the radial phased array is an annular array. When the annular array is excited, all of the emitted acoustic lines have a common origin lying at the center of the annular array. An annular array is used to obtain a 360 degree scan. A 360 degree scan, however, is not always necessary for every application. In particular, in another preferred embodiment shown in FIG. 3 the radial array 22' may be formed by a curved linear phased array which does not form an annulus and only provides less than a 360° scan. In another preferred embodiment shown in FIG. 4, the radial array 22" may be formed by a substantially planar linear phased array which provides less than a 360° radial scan. A radial array, as that term is used in the present invention, is any array that generates a scan in a plane perpendicular to the longitudinal axis of the catheter when the array is excited. If the radial array is formed by a linear or curved linear phased array the scan obtained may be linear, sector or VECTOR™ format.

Radial phased ultrasonic transducer array 22 in FIG. 2 is formed by a plurality of transducer elements 32 sequentially arranged circumferentially so that it is preferably concentric with the body 12. The radial phased array 22 is preferably formed by 64 elements having an elevation dimension of 2.5 mm spaced on a 0.11 mm pitch. In a preferred embodiment the radial phased array 22 is annular to provide a 360° scan. An annular array may be manufactured from an annulus of piezoelectric material or, alternatively, an annular array may be formed by wrapping a flat transducer array that has been partially diced around a backing block support. Alternatively the radial phased array 22 may be formed by fewer elements and thus provide less than a 360° scan.

As is well known in the art, conventional ultrasound transducers are typically constructed of piezoelectric material such as PZT. In a preferred embodiment, the piezoelectric material for arrays 20 and 22 is preferably 3203HD sold by Motorola Ceramics of Albuquerque, N. Mex. Preferably, each transducer element includes two matching layers. The

matching layer adjacent to the PZT is an epoxy loaded with alumina or lithium aluminum silicate and/or metal power such as tungsten preferably 325 mesh and possesses an acoustic impedance of approximately 8-10 MRayls. The second matching layer—further from the PZT—is preferably an unfilled epoxy possessing an impedance of approximately 2.5 MRayls. The arrays 20 and 22 are constructed using well known techniques which involve laminating the matching layers, an electroded slab of PZT and a flexible circuit onto a thin backing block substrate. Since a very high acoustic loss is desired, it may be preferable to form the backing block from polymeric particles which have been fused to form a macroscopically rigid structure having remnant tortuous permeability, as described in U.S. Pat. No. 5,297,553, assigned to the assignee of this invention. Once the structure has been laminated, individual elements are defined by dicing through the matching layers, PZT and partially into the backing block as is well known. Thereafter, the substrate can be bent to final shape.

IC multiplexers such as those described in Proudian U.S. Pat. No. 4,917,097 and Eberle U.S. Pat. No. 5,368,037 may be incorporated in the distal end of the catheter to couple the signal conductors of the ultrasonic transducer array to the electronics of the ultrasound system. Alternatively, IC multiplexers which allow a selection between the channels of the radial phased array and the channels of the linear phased array may be used thereby saving space, since when a device smaller than about 2-3 mm in diameter incorporates an ultrasonic array it may become necessary to incorporate multiplexers in the device.

FIG. 6 is a schematic illustrating a catheter inserted into a chamber of the heart of a patient. In the example shown in FIG. 6, the catheter is inserted into the right atrium of the patient's heart so that the radial phased array 22 can be used to image structures such as the crista terminalis and the coronary sinus orifice as well as give an indication of relative position of the catheter within the chamber. While still in the right atrium, the linear phased array 20 can be used to image the left atrium and left ventricle as well as other structures such as the mitral, tricuspid, aortic and pulmonary valves as an example. In addition, while the radial phased array 22 does not have good image resolution in the far field, it does provide a 360 degree view and outline of the heart chamber which can assist in understanding and interpreting the images obtained by the linear phased array 20. This can be very useful, for example, to an electrophysiologist who is not typically familiar with ultrasound images of the heart. The catheter is inserted into the heart by well known techniques which need not be described here in detail.

By utilizing both types of arrays 20 and 22 in one catheter, the cardiac structures in the very near field can be visualized with the radial phased array 22 and structures deeper or on the opposite side of the heart can be imaged with the linear phased array 20.

While the catheters shown in FIGS. 1-5 has the linear phased array 20 located proximal of the radial phased array 22, their positions can be reversed so that the radial phased array 22 is proximal of the linear phased array 20.

In addition, to provide good near and far field resolution, the catheters according to the preferred embodiment shown in FIGS. 1-5 can be used to reconstruct three dimensional images. More particularly, one array may be used as an imaging array and the other array may be used as a tracking array. For example, if the radial phased array is used as the imaging array and the linear phased array is used as the

Alternatively, if the linear phased array is used as the imaging array and the radial phased array is used as the tracking array, multiple two dimensional image data sets are acquired using the linear phased array. The catheter is rotated and the radial phased array acquires multiple data sets which are analyzed to determine the extent of rotation between frames. This provides enough locating information to allow the multiple two dimensional image data sets to be assembled into a three dimensional volume. Alternatively, both arrays 20 and 22 may be used as tracking arrays.

FIG. 7 is a block diagram of an ultrasonic imaging system according to a preferred embodiment of the present invention. The following discussion will first present a system overview, and then a detailed description of select components of the system.

The system 100 includes a beamformer system/signal detector 102 which includes both transmit and receive beamformers and is connected via a multiplexer/demultiplexer 104 to the catheters shown in FIGS. 1-5. If both arrays are operating in a conventional mode where the active transducer aperture is operated simultaneously in a phased manner then any conventional device such as the Acuson XP may be used for element 102. If the arrays are being operated in a synthetic aperture mode, i.e., in which the elements of the array are operated in a sequential rather than simultaneous mode, then it is necessary for the system to store the receive element signals in a temporary store until all of the transmit-receive element combinations have been received. Once all the echo signals have been received then the data in the temporary storage registers are delayed and summed to produce a beamformed signal. Systems for implementing this type of synthetic focusing by temporarily storing single channel data until all channel data has been received are well known, for example, see Proudian U.S. Pat. No. 4,917,097. The system preferably accumulates multiple signals for each transmitter-receiver pair so that signal averaging is achieved thereby resulting in an improvement in the signal to noise ratio. Alternatively instead of using a common transducer element for both transmitter and receiver a separate receiver can be used for each transmitter channel selected. Such a method is described by O'Donnell et al. in "Synthetic Phased Array Imaging of coronary Arteries With An Intraluminal Array," Proceedings of the 1995 IEEE Ultrasonics Symposium, pp. 1251-1254 (1995). Individual elements are sequentially

The beamformer system/signal detector **102** sends excitation signal pulses to the arrays **20** and **22** and supplies summed returning echoes to a signal detector. The output of the signal detector is supplied to a scan converter **124**. The beamformer system/signal detector **102** accumulates data from the array elements in arrays **20** and **22** and forms beamformed acoustic line outputs. The scan converter **124** controls an output display **126** to display preferably the two images generated by the two arrays **20**, **22**. In a preferred embodiment, the output display **126** displays the views obtained from the linear phased array **20** and the radial phased array **22** simultaneously on a split screen. Alternatively, the operator may flip back and forth between views. The possible display options will be described in greater detail hereinafter.

The frames of image data in the storage array **130** are applied to a computer **136**. It is these frames that are used to form the displayed representation of the region of interest. The tracking frames stored in storage array **132** are not necessarily registered to create a displayed reconstruction of

In order to estimate movement of the catheter 10 between successive frames of the image data, the tracking information from the tracking array data storage array 132 is supplied to a motion estimator 138. The motion estimator 138 compares sequences of frame data from the tracking array 22 to estimate a component of motion of the catheter 10 between the respective frames. This estimate of the component of motion is smoothed in logic 140, and then applied to a calculator 142 that calculates a vector value defining the best estimate of the movement between selected frames of the data stored in the image data storage array 130. This vector is then applied as another input to the computer 136.

Common signal conductors can be used between the beamformer/signal detector **102** and the housing for the catheter **10**. In the housing, individual signals are routed between the signal conductors and the transducer elements of the arrays **20** and **22** by high voltage analog switches or multiplexers.

With respect to the radial array, the output of the beamformer are polar in format. For measuring rotational motion rather than Cartesian motion, it is simpler to retain the acoustic line data in polar format, i.e., not scan converted. Typically, the beamformer outputs lines are detected to form unipolar signals and are scan converted to digital quantities. FIG. 8 illustrates how a subset of beam data appears in reality, i.e. scan converted into Cartesian coordinates. It is much simpler, however, to unwrap the axial display shown in FIG. 8, i.e. do not scan convert it. FIG. 9 illustrates how this data is unwrapped to form the straight polar case. The increment between successive beam lines is simply their angular separation, for example, 5 degrees. With respect to detecting the motion of pixel values from Line 1 to Line etc., it is evident that by using polar coordinates the correct answer for rotation is arrived at more simply.

Since one is able to collect image data from both arrays and use one or both sets for tracking motion of the other plane, various display options exist.

FIG. 10 illustrates a display of the linear phased array. The angle of probe rotation with respect to some user defined arbitrary starting point has been measured. This angle is an indication of the relative angular direction of the image frame produced by the linear phased array and may be displayed as a circular icon as shown in FIG. 10 and/or a numeric output as is also displayed. The circular icon assumes that the user defined origin is at the top of the circle (for example) and the angular rotation of the probe with

FIG. 11 illustrates a display of the radial phased array. The radial display is presented and depth of penetration as detected by motion sensed from the linear array is also displayed. Again the reference point for the start of motion detection is arbitrary and the user should have the option of resetting it by, for example, selection of a key on a keyboard. An icon display for the detected depth relative to the last resetting of the depth measurement is also shown in FIG. 11. Preferably the icon is in the form of a ruler like object with an arrow pointing to the current position. Optionally, a numeric display indicating millimeters of penetration is also provided.

FIG. 13 illustrates a display of images from both the linear phased array and the radial phased array. In this preferred embodiment the radial image display is rotated according to the detected rotation angle such that the display rotation completely compensates for the physical device rotation. Thus, the image appears to remain static though the image is moving with respect to the array. If the system detects that an arbitrary object has moved 20 degrees anticlockwise, the system signals the scan converter to rotate the image 20 degrees clockwise to compensate. The concept of the detecting image motion and altering the display to correct for it is described in considerable detail in Bamber U.S. Pat. No. 5,538,004.

FIG. 16 illustrates the distal region 18" of still another preferred embodiment of a catheter according to the present invention. In this preferred embodiment a curved linear phased array 300 is disposed distal of the first radial phased array 302 and is curved. Optionally a second radial phased array 304, shown may be provided proximal of the first radial phased array 302.

While this invention has been shown and described in connection with the preferred embodiments, it is apparent that certain changes and modifications, in addition to those mentioned above, may be made from the basic features of